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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

VAKILI, ZOHREH

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 11/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/804,760	<b>Applicant(s)</b> SACKS ET AL.	
	<b>Examiner</b> Zohreh Vakili	<b>Art Unit</b> 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                               | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                      | 5) <input type="checkbox"/> Notice of Informal Patent Application                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112 first paragraph***

#### **LACK OF WRITTEN DESCRIPTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH:**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-5 are directed to encompass derivatives, precursor and inhibitors which only correspond in some undefined way to specifically instantly disclosed chemicals. None of these derivatives, precursor and inhibitors meet the written description provision of 35 USC § 112, first paragraph, due to lacking chemical structural information for what they are and chemical structures are highly variant and encompass a myriad of possibilities. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath, Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the

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'written description' inquiry, *whatever is now claimed*. (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

With the exception of the above specifically disclosed chemical structures, the skilled artisan cannot envision the detailed chemical structure of the encompassed derivatives, analogs, etc., regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The chemical structure itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence. Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the

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written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

Therefore, only the above chemically structurally defined chemicals, but not the full breadth of the claim(s) meet the written description provision of 35 USC § 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC § 112 is severable from its enablement provision. (See page 1115).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peeters (WO 94/00132) in view of Howard et al. (GB 2 280 110).

Peeters discloses the treatment of Alzheimer's disease with guanosine and precursors and/or derivatives thereof, including the elected species xanthosine, as well as guanine, inosine, xanthine, hypoxanthine, 5' inosinic acid, and mono-, di- and triphosphates of guanosine. See claims 1-12, and amended claims 1-12, at pages 14-17 of the English language translation provided herewith. Thus, Peeters discloses pharmaceutical compositions comprising each of those compounds.

Claim 1 recite that the compositions contain a "daily dosage amount" of from 100 to less than 1,000 mg. Properly construed at its broadest, the recitation "daily dosage amount" is merely a recitation of intended use, and the claims encompass any composition which can be administered at the claimed daily rate of administration.

Peeters does not explicitly disclose the amounts of any dosage forms, although Peeters does disclose that oral dosage forms such as tablets and gelcaps are suitable for the disclosed compositions. See page 11 of the translation. Peeters also discloses that the elected species xanthosine should be administered at dosages of from 20 mg/kg/day to 150 mg/kg/day. See translation at page 11, lines 3 and 4. Assuming a 50 kg person, this dosage would result in an administration of compositions comprising 1 to

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7.5 grams per day. The artisan of ordinary skill clearly would have recognized that a suitable method of administering 1 gram of xanthosine, or more, per day would have been by administering in 500 mg oral dosage forms. Official notice is taken of the fact that the determination of suitable dosage regimens for the therapeutic methods in Peeters, including the use of 500 mg dosage forms, was clearly well within the purview of the artisan of ordinary skill at the time of applicant's invention. Therefore, the claims must be considered obvious under § 103(a), absent some demonstration of an unexpected result coming from the claimed use of dosage forms containing less than 1 gram, or no more than 500 mg of xanthosine.

As discussed above, Peeters renders obvious the treatment of Alzheimer's disease using compositions comprising the claimed amounts of guanosine and precursors and/or derivatives thereof, including the elected species xanthosine, as well as guanine, inosine, xanthine, hypoxanthine, 5' inosinic acid, and mono-, di- and triphosphates of guanosine. Peeters differs from the claims in that Peeters does not disclose the inclusion of the elected additional ingredient vitamin C in described compositions.

However, Howard et al. discloses that vitamin C should be included in a regimen of treating Alzheimer's. See claim 5 on page 27, also claim 14 on page 29. Thus, the artisan of ordinary skill, reasonably expecting the vitamin C of Howard et al. to be beneficial in Peeters' method of treating Alzheimer's, clearly would have been motivated to have included Howard's et al. vitamin C in the therapeutic regimen disclosed by Peeters.

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The intended rate of administration does not, and cannot, change the product itself. Thus, despite the recitation in claim 1 regarding a "daily dosage"; all that the claim requires is that the composition comprises the claim-designated amounts of the therapeutic ingredient. One of ordinary skill preparing orally administrable compositions according to Peeters disclosure clearly would have been motivated to have prepared those compositions in dosage forms containing amounts of the ingredients which would have been suitable for oral administration. Such dosage forms clearly encompass the amounts of the uric acid precursors recited in the pending claims. Because the intended dosage regimen does not change the product itself, and because Peeters suggests preparing dosage forms containing the claimed amount of uric acid precursors.

Note that it is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten*, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

### Conclusion

Rejection of claims 1-5 are deemed proper.

No claims of the present application are allowed.



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Any inquiry concerning this communication should be directed to Zohreh Vakili, telephone number 571-272-3099. The examiner can normally be reached from 8:30 a.m. to 6:00 p.m., Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached at 571-272-0718. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.ushpo.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic business Center (EBC) at 866-217-9197 (toll-free).

Zohreh Vakili  
Patent Examiner  
Art Unit 1614

October 27, 2006

 11/10/06  
ARDIN H. MARSCHEL  
SUPERVISORY PATENT EXAMINER